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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,932	02/08/2002	Robert J. Nordstrom	MDS-022C1	1037

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EXAMINER	
ROY, BAISAKHI	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,932	NORDSTROM ET AL.	
	Examiner	Art Unit	
	Baisakhi Roy	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,26-34,36-38,40-44,46,47 and 49-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24, 26, 27-34, 36-38, 40-44, 46, 47, and 49-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6/2/05 have been fully considered but they are not persuasive. In reference to the use of monochromatic radiation, Utzinger et al. teach the use of monochromatic excitation (col. 8 lines 10-13 lines 22-25 lines 61-67) to determine whether the specimen has a known condition by using fluorescence data and if it is indeterminate, using reflectance data to classify the test specimen. Gombrich et al. also teach the use of single excitation wavelength (col. 4 line 26-30). Therefore, the previous rejection still stands.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 24, 26-34, 36-38, 40-44, 46, 47, and 49-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6385484. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the application claims are an obvious broadening of the patent claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 24-32, 36-42, 46, 47, and 49-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Utzinger et al. (6571118).

Regarding claims 24, 32, 38, 42, and 44, Utzinger et al. disclose a method and system of determining a condition of a cervical tissue by obtaining optical information by using a data collection module to obtain reflectance spectral data from a cervical tissue and a computation module to determine whether fluorescence spectral data from said cervical tissue is definitive of said cervical tissue having a known condition, obtaining and processing reflectance spectral data of said tissue using reference reflectance

spectral data from a plurality of reference specimens having said condition, and determining said condition of said cervical tissue based on processing and optical information (abstract, col. 2 lines 24-39, col. 3 lines 48-59, col. 4 lines 7-32 lines 57-63, col. 23 lines 4-8, col. 25 lines 56-67, col. 26 lines 20-67, col. 31 lines 49-67, col. 32 lines 1-20).

Regarding claims 26, 27, 36, 37, 40, 41, 46, 47, and 49-52, Utzinger et al. teach said method and system to include determining a condition or a known state of health comprising one of the conditions of normal squamous tissue, metaplasia, CIN I, and CIN II/III (col. 25 lines 53-67, col. 26 lines 20-38, col. 35 lines 4-24, col. 36 lines 1-43).

Regarding claims 28-31, Utzinger et al. teach said reference reflectance spectral data to comprise of an average amplitude for each of plurality of wavelengths, determining a residual amplitude at each of plurality of wavelengths by subtracting an average amplitude of said reference reflectance spectral data from an amplitude of said reflectance spectral data of said cervical tissue, and where determining said condition of said cervical tissue comprises comparing the residual amplitude at each of said wavelengths to one or more sets of reference residual reflectance spectral data (col. 18 lines 41-62, col. 21 lines 1-12 lines 46-67, col. 22 lines 1-16, col. 23 lines 4-18, col. 26 lines 20-50, col. 29 lines 21-47, col. 30 lines 58-67, col. 31 lines 49-67, col. 32 lines 1-20 lines 56-67, col. 33 lines 1-40, col. 35 lines 4-24, col. 39 lines 20-48, fig. 20-48).

3. Claims 24, 32-34, 38, and 42-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Gombrich et al. (5999844). Gombrich et al. disclose a method and system and system of determining a condition of a cervical tissue by obtaining optical

information by using a data collection module to obtain reflectance spectral data from a cervical tissue and a computation module to determine whether fluorescence spectral data from said cervical tissue is definitive of said cervical tissue having a known condition, obtaining and processing reflectance spectral data of said tissue using reference reflectance spectral data from a plurality of reference specimens having said condition, and determining said condition of said cervical tissue based on processing and optical information such as video information and optical image (col. 3 lines 59-67, col. 4 lines 1-22 lines 59-67, col. 5, col. 6 lines 62-67, col. 7 lines 1-15, col. 8 lines 20-67).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 33, 34, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Utzinger et al. in view of Gombrich et al. Utzinger et al. do not explicitly teach the use of video information and optical image. Gombrich et al. disclose a method and apparatus for determining a condition of cervical tissue by obtaining optical information with the use of video information and optical image (col. 3 lines 59-67, col. 4-5. It would have therefore been obvious to one of ordinary skill in the art to use the image display teaching by Gombrich et al. to modify the teaching by Utzinger et

al. for the purpose of obtaining additional optical information of the tissue of interest with adequate display means of the tissue data.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for relevant references of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. R.

BR

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